510(k) SUMMARY
Houston Medical Robotics, Inc. Euclid™ Tier 1 Mini Access System

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, section 807.92.

Sponsor's Name and Address:
Houston Medical Robotics, Inc.
17225 El Camino Real, Suite 350
Houston, Texas 77058

Contact Person:
Darla J. Elkin
Elkin RC, LLC
42 North Chantsong Circle
The Woodlands, TX 77382
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Date Summary Prepared:
May 20, 2011

Device Trade Name:
Euclid™ Tier 1 Mini Access System

Product Code:
ITX

Regulation Number:
21CFR 892.1570

Classification:
Class II

Common Name:
Diagnostic ultrasonic transducer

Predicate Devices:
The WAND™ (K081697)
Ultra-Pro II Needle Guidance System (K093713)

Device Description:

The Euclid™ Tier 1 Mini Access System is designed to provide the medical practitioner with the capability to accurately and reliably insert a guidewire into a vessel. The device consists of (1) the Euclid™ Tier 1 Mini Base Kit containing the sterile disposable device assembly consisting of a needle (18/21 Gauge) and guidewire (0.18" diameter x 40 cm length), a Euclid™ Ultrasound Imaging Screen Overlay, and IFU; and (2) the Euclid™ Tier 1 Mini Transducer Adapter Kit which contains a Euclid™ Transducer Adapter and IFU.

Intended Use:

The Euclid™ Tier 1 Mini Access System is used to facilitate the placing of a needle and guidewire into a targeted anatomical location.

Comparison of the Technological Characteristics of the New Device and Predicate Devices:

Features	Euclid™ Tier 1 Mini Access System	The WAND Microaccess Safety Introducer	Ultra-Pro II Needle Guidance System
K#	K111426	K093022	K093713
Disposable Components	Sterile Disposable: • Needle • Guidewire	Sterile Disposable: • Needle • Guidewire • Sheath	Sterile Disposable: • Disposable Needle Guide • Cover
Reusable Component	None	None	Bracket to hold Ultrasound Transducer
Guidewire	Nitinol 0.018"	Nitinol 0.018"	N/A
Angle Needle Path	Yes (Adjustable & Fixed During Use)	No	Yes (Fixed)
Placement	Manual	Manual	Manual
Ultrasound Guided Procedure	Yes Couples with commercially available ultrasound	Yes Labeling suggests use of commercially available image guidance.	Yes Couples with commercially available ultrasound.
Vessel Depth Setting	Yes	No	Yes
Needle	18 /21 GA thin-walled stainless steel	21 GA thin-walled stainless steel	N/A
Ultrasound Visibility	Yes	Yes	No
Visual Display of Vessel Access	Yes, external Ultrasound Screen	Yes, Flashback window	Yes, external Ultrasound Screen
EtO Sterilized	Yes	Yes	Yes

Performance Testing

Results of bench studies conducted on the Euclid™ Tier 1 Mini Access System demonstrate the System to be as safe and as effective as the predicate device based on the biocompatibility of the materials used, sterilization validation, bench testing and verification and validation in animal models. The following studies were conducted on the Euclid™ Tier 1 Mini Access System and acceptance criteria were met:

- **Functional Verification**
  Benchtop testing (Guidewire insertion) to the functional extremes (5mm and 60mm;

- **Shipping Integrity**
  Simulated shipping conditions followed by device and packaging inspection, guidewire insertion in benchtop model to functional extremes (5mm and 60mm), pouch seal strength testing, and dye penetration testing;

- **Accelerated Aging**
  Aging to 6 months followed by functional testing (guidewire insertions to 5mm and 60mm), pouch seal strength testing, and dye penetration testing;

- **Animal Validation**
  Guidewire insertion in animal model by end user; and

- **Biocompatibility Testing**
  Materials tested per ISO 10993, including: Systemic Toxicity, Intracutaneous Toxicity, Implantation, Cytotoxicity, Hemolysis, Pyrogenicity, and Sensitization.

Conclusion

The Euclid™ Tier 1 Mini Access System is substantially equivalent to the predicate devices. The indication for the devices is substantially equivalent. The technological design and functional characteristics of placement of a guidewire using ultrasound guidance with a sterile disposable device are all substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Houston Medical Robotics, Inc.
c/o Ms. Darla J. Elkin
Elkin RC, LLC
42 North Chantsong, Circle
The Woodlands, TX. 77382

Re: K111426
Trade Name: Euclid™ Tier 1 Mini Access System
Regulation Number: 21 CFR 892.1570
Regulation Name: Diagnostic Ultrasonic Transducer
Regulatory Class: II (two)
Product Code: ITX
Dated: February 24, 2012
Received: February 27, 2012

Dear Ms. Elkin:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K111426

Device Name: Euclid™ Tier 1 Mini Access System

Indications for Use:

The Euclid™ Tier 1 Mini Access System is used to facilitate the placing of a needle and guidewire into a targeted anatomical location.

Prescription Use _X_ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

M.A. Hillebrenner
Concurrence of ~~CDRH~~, Office of Device Evaluation (ODE)
(Division Sign-Off)
Division of Cardiovascular Devices

510(k) Number K111426